REMARKS

This amendment responds to the Final Office action mailed October 21, 2003. Claims 13-16 and 26 are currently pending in the present application. Applicants have amended claims 13 and 16 to further clarify the invention and to correct typographical errors. Support in the specification for the amendments may be found in the present specification, *e.g.*, on page 5, lines 2-14; and in Example 4. Support for newly added claim 26 is found, *e.g.*, on page 4, line 22 to page 5, line 3; and in Example 4. No new matter has been added.

THE REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, SHOULD BE WITHDRAWN

The Examiner has maintained the rejection of claims 13-17 for lack of written description under 35 U.S.C. § 112, paragraph one, for the alleged failure of the disclosure to provide an adequate written description for the large genus of estrogen-regulated markers. In particular, the Examiner contends that there is a lack of written description for the claimed method for a genus of nucleic acids whose function is not known. Applicants respectfully assert that the requirements for written description under 35 U.S.C. § 112, paragraph one, have been fully satisfied; as such, the rejection should be withdrawn for the reasons detailed below.

Applicants respectfully remind the Examiner that the legal standard for the written description requirement under 35 U.S.C. § 112, paragraph one, has been set forth by the Court of Appeals for the Federal Circuit (*see, Vas-Cath v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991)). To satisfy the requirement, an applicant must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention" (*Vas-Cath v. Mahurkar*, 935 F.2d at 1563-64 and MPEP § 2163 at page 2100-159). Possession may be shown in a variety of ways, including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of structural chemical formulas that show the invention was complete or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention (*see, e.g., Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 68 (1998); *University of California v. Eli Lilly Co.*, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 18 U.S.P.Q.2d 1016, 1021 (Fed. Cir. 1991); and MPEP § 2163 at page 2100-159). Further, an applicant may show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, *i.e.*, complete or

partial structure (*see* MPEP § 2163, pages 2100-165 to 2100-166). For some biomolecules, examples of identifying characteristics include a sequence (*see* MPEP § 2163 at page 2100-166).

Applicants assert that the instant specification fully satisfies the written description requirement set forth by the Federal Circuit. Applicants respectfully remind the Examiner that the specification discloses the nucleotide sequence, *i.e.*, structure, of at least 75 examples of estrogen-regulated markers (ERMS) that may be used in accordance with the claimed assays (*see, e.g.*, page 18, lines 1-35; page 19, lines 29-36; page 20, lines 1-7; page 20, lines 14-21; Example 2, and Table I). Describing a nucleic acid by disclosing its nucleotide sequence, a sufficiently detailed, relevant identifying characteristic, fully satisfies the written description requirement for biological molecules as set forth by the Federal Circuit. The Examiner's citation to NCI-CGAP (accession number AA747315, 1999), which discloses a nucleotide sequence that is identical to the claimed sequence of SEQ ID NO:1 (formerly SEQ ID NO:57) in fact supports Applicants' present argument that disclosure of an identifying characteristic such as a nucleotide sequence fully satisfies the written description requirement, and that a further description of function is not required. Even so, Applicants have identified at least 75 examples of ERMs, including SEQ ID NO: 1, based upon experimental evidence that expression of these markers is regulated in response to modulation of the estrogen receptor (*see* page 11, lines 13-21; and Example 2), thereby providing both structural and functional support for the identified ERM sequences.

Further, the written description requirement for a claimed genus may be satisfied through sufficient description of a number of species by disclosure of relevant, identifying characteristics, *i.e.*, structure, sufficient to show the applicant was in possession of the claimed genus (*see, Eli Lilly* at 1406 and MPEP § 2163 at 2100-168). Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces (*see*, MPEP § 2163 at 2100-168). *See also Eli Lilly*, 43 U.S.P.Q.2d at 1406, where the Federal Circuit states that "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus..." (emphasis added). Thus, the written description requirement for the claimed genus (*i.e.*, estrogen-related markers responsive to estrogen and/or a candidate SERM) has been sufficiently satisfied through sufficient description of a representative number of species (*i.e.*, disclosing the nucleotide sequences of at least 75 ERMs). Such a description is clearly

sufficient to show that Applicants were in possession of the claimed genus at the time the application was filed.

For the forgoing reasons, Applicants respectfully request that the rejections under 35 U.S.C. § 112, first paragraph, of claims 13-17 be withdrawn.

THE REJECTIONS UNDER 35 U.S.C. § 102 SHOULD BE WITHDRAWN

The Examiner has maintained the rejections of claims 13 and 15-17, which are drawn to methods for identifying a selective estrogen receptor modulator, as being anticipated by Mendelsohn *et al.* (United States Patent No. 5,728,534, dated Mar. 17, 1998) ("Mendelsohn"). Applicants respectfully submit that the Examiner has mischaracterized Mendelsohn. In particular, the Examiner contends that Mendelsohn teaches the screening assays of the instant invention, and thereby anticipates the claims. This rejection is in error for the reasons detailed below and should be withdrawn.

Applicants respectfully remind the Examiner that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference (*see, Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) and MPEP § 2131 at 2100-70). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the...claim" (*see, Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) and MPEP § 2131 at 2100-70). Applicants point out that the Mendelsohn reference does not satisfy the requirements for anticipation as set forth by the Federal Circuit.

In brief, the present invention relates to an assay for the identification of a SERM, a selective estrogen-responsive modulator, whereby the assay comprises contacting cells expressing an estrogen-regulated marker(s) (ERM) with estrogen and a test agent, and determining the expression of at least one endogenously-expressed ERM in the cells and comparing the levels of expression in the presence and the absence of the test agent, and therefrom determining whether the test agent is a SERM. A difference in expression levels of the ERM indicates that the test agent is a SERM (*see* Example 4). Such expression can be measured by RNAse protection assays (*see* page 17, line 15 to page 18, line 3 and Example 4 of the instant specification).

In contrast, the assays described in Mendelsohn are for the identification of vasoprotective agents based on the ability of a test agent with known estrogen receptor inductive effects to selectively induce the activity of a non-native reporter construct containing an upstream regulatory region of an estrogen receptor responsive gene, or an

isolated estrogen receptor recognition element (ERE) operably linked to a nucleotide sequence encoding a detectable protein, *e.g.*, luciferase (*see* Mendelsohn, col. 11, lines 11-36). Thus, Mendelsohn is clearly distinguishable from Applicants' presently claimed invention.

In summary, Mendelsohn does not set forth "each and every element as set forth in the claim." As such, the Mendelsohn reference cannot form the proper basis of a rejection of the present claims under 35 U.S.C. § 102(b).

Applicants respectfully request that, for the forgoing reasons, the anticipation rejection of claims 13 and 15-17 be withdrawn.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks intended to put the claims in form for allowance. Withdrawal of the Examiner's rejections and an allowance of the application are earnestly requested. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned at (858) 314-1130, if a telephone call could help resolve any remaining items.

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